September 5, 2000

EA-00-178

Richard G. Johnson
Vice President
Imaging Operations
Mallinckrodt, Inc.
675 McDonnell Boulevard
P. O. Box 5840
St. Louis, MO 63134

SUBJECT: NRC FOLLOWUP TO AUGMENTED INSPECTION TEAM (AIT) FINDINGS AND INSPECTION REPORT 030-00001/2000-003(DNMS)

Dear Mr. Johnson:

This refers to the inspection conducted on July 17 - 19, and August 3 - 4, 2000, at the Mallinckrodt, Inc., Maryland Heights, Missouri, facility. The purpose of the inspection was to followup on the findings of an Augmented Inspection Team (AIT) inspection performed on May 4 through 26, 2000, to review Mallinckrodt's identification of multiple occupational extremity exposures in excess of the NRC limit of 0.5 sievert (50 rem). The findings of the AIT were transmitted to you in our July 14, 2000 letter. The enclosed report presents the results of this inspection. At the conclusion of the inspection, the findings were discussed with you and members of your staff.

Based on the results of this inspection, five apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The apparent violations consist of failures to: 1) control activities such that the extremity dose to individual workers does not exceed 0.5 sievert (50 rem) shallow dose equivalent (33 examples ranging from 0.5 to 6 sievert (50 to 600 rem)); 2) use procedures and engineering controls to maintain doses as-low-as-is-reasonably-achievable; 3) make necessary surveys under the circumstances to ensure that the assigned shallow dose equivalent was for the part of the extremity receiving the highest exposure; 4) conduct a radiological evaluation of the generator manufacturing line prior to its first use, in accordance with license commitments; and 5) make necessary surveys under the circumstances to ensure that extremity doses are within regulatory limits. Accordingly, no Notice of Violation is presently being issued for these inspection findings. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open predecisional enforcement conference to discuss these apparent violations has been scheduled for September 28, 2000, at 9:00 a.m. (CT) in the Region III office, 801 Warrenville Road, Lisle, Illinois. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to enable the NRC to make an enforcement decision, such as a common understanding of the facts, root causes, missed

opportunities to identify the apparent violations sooner, corrective actions, significance of the issues and the need for lasting and effective corrective action. In particular, we expect you to address Mallinckrodt's failure to recognize the significant differences between the radiation doses recorded by extremity monitoring devices and the fingertip doses received when handling unshielded containers of radioactive material. In addition, this is an opportunity for you to point out any errors in our inspection report and for you to provide any information concerning your perspectives on: 1) the severity of the violations, 2) the application of the factors that the NRC considers when it determines the amount of a civil penalty that may be assessed in accordance with Section VI.C.2 of the Enforcement Policy, and 3) any other application of the Enforcement Policy to this case, including the exercise of discretion in accordance with Section VII. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available **electronically** for public inspection in the NRC Public Document Room **or** from the *Publicly Available Records (PARS) component of NRC's document system (ADAMS)*. *ADAMS is accessible from* the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

Sincerely,

/RA/

J. E. Dyer
Regional Administrator

Docket No. 030-00001
License No. 24-04206-01

Enclosures: 1. Inspection Report 030-00001/2000-003(DNMS)
2. Excerpt from NRC Information Notice 96-28

See Attached Distribution

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REGION III

Docket No:	030-00001
License No:	24-04206-01
Report No:	030-00001/2000-003(DNMS)
Licensee:	Mallinckrodt, Inc.
Location:	2703 Wagner Place Maryland Heights, MO 63043
Dates:	July 17 - 19, 2000 August 3 - 4, 2000
Exit Meeting:	August 31, 2000
Inspectors:	Geoffrey C. Wright, Chief, Materials Inspection Branch Jamnes L. Cameron, Principal Inspector
Approved By:	Cynthia D. Pederson, Director Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Mallinckrodt, Inc.
Maryland Heights, MO
NRC Inspection Report 030-00001/2000-003(DNMS)

This was a special inspection to review the findings of an Augmented Inspection Team (AIT) inspection conducted May 4 through 26, 2000. The AIT reviewed the circumstances of multiple licensee-reported extremity exposures in excess of the NRC limit of 0.5 sievert (50 rem) shallow dose equivalent (SDE). The exposures resulted from two routine licensee operations, that involved the direct handling of unshielded containers of radioactive material, and an exposure event that occurred on March 31, 2000. Details of the AIT findings are described in the AIT Inspection Report 030-00001/2000-002(DNMS), transmitted July 14, 2000.

The inspection identified five apparent violations. The apparent violations consist of failures to: 1) control activities such that the extremity dose to individual workers does not exceed 0.5 sievert (50 rem) SDE (33 examples ranging from 0.5 to 6 sievert (50 to 600 rem)); 2) use procedures and engineering controls to maintain doses as-low-as-is-reasonably-achievable (ALARA); 3) make necessary surveys under the circumstances to ensure that the assigned SDE was for the part of the extremity receiving the highest exposure; 4) conduct a radiological evaluation of the generator manufacturing line prior to its first use, in accordance with license commitments; and 5) make necessary surveys under the circumstances to ensure that extremity doses are within regulatory limits.

The root cause of the exposure resulting from handling the generator column was the individual's misunderstanding of the difference between radioactive contamination and radiation. The individual believed that the gloves he wore provided him adequate protection since he perceived the radiological hazard to have been contamination, rather than penetrating radiation. Based on interviews of numerous licensee staff, this perception was limited to the individual.

The cause of the other exposures was the failure of plant staff and management, including health physics (HP) personnel, to recognize the significant differences between radiation doses recorded by extremity monitoring devices and fingertip doses when handling unshielded containers of radioactive material. In some instances, the fingertip doses were 100 times the doses recorded by the monitors. This misconception contributed to the failure of Sterility Laboratory personnel to consistently use syringe and vial shields to maintain their extremity doses ALARA. Sterility Laboratory personnel were concerned that the introduction of additional shielding and other sound radiation protection techniques would result in false-positive sterility tests. False-positive tests would result in the unnecessary rejection of an entire manufacturing lot. Laboratory and HP personnel did not recognize the radiological impact of their actions, since they relied almost exclusively on the results of personnel monitoring, which indicated that doses were within regulatory limits.

The lack of an aggressive questioning attitude toward extremity doses in the areas reviewed during this inspection directly contributed to the apparent violation for failure to make necessary surveys to ensure that the assigned SDE was for the part of the extremity receiving the highest exposure. Although the licensee had initiated dose reduction efforts to lower extremity doses in some manufacturing areas, the impetus for those efforts were based on the results of personnel monitoring.

The inspector was not able to determine a root cause for the apparent failure to conduct a pre-production radiological evaluation of the generator manufacturing line. However, since the issuance of Amendment No. 52 to License No. 24-04206-01 on March 7, 1994, which required Mallinckrodt to perform these assessments in accordance with license commitments, the generator manufacturing line was the only process identified for which a pre-production assessment had not been performed by the Radiation Safety Committee.

The licensee's corrective actions implemented as of this inspection were adequate. Based on the preliminary AIT findings, the NRC issued a Confirmatory Order Modifying License (Order) on June 22, 2000. The main elements of the Order required Mallinckrodt to retain an independent organization to perform assessments of its radiation protection program and manufacturing processes. Additional, long-term corrective actions may likely result from the findings of the assessments.

The NRC contracted with a medical consultant to review the initial exposure event involving the handling of a molybdenum-99 generator column. The consultant did not expect any health effects as a result of the exposure. The consultant did not render an opinion on the chronic exposures involving the hand-labeling of vials or Sterility Laboratory activities.

1.0 Summary of Events and Exposure Calculations

a. Inspection Scope

The inspection included a followup to the initial descriptions of the three exposure events. The review included the results of the licensee's dosimetry studies and interviews of personnel.

b. Observations and Findings

A detailed description of each exposure event and the initial dose assessments performed for the exposed individuals can be found in the Augmented Inspection Team (AIT) Inspection Report 030-00001/2000-002(DNMS). The following subsections provide the results of NRC's followup to the events and the licensee's preliminary plans for refining its dose assessments.

Generator Column Exposure Event - Update

As described in the AIT Inspection Report, the initial sequence of events indicated that a contract employee (Individual A) handled a generator column containing (19 curies) of molybdenum-99 and (8 curies) of technetium-99m for up to 50 seconds while at the rework station of the generator manufacturing line. Preliminary information indicated that the employee held the column in his left hand using the thumb and index finger. Based on that information, the licensee's contractor estimated the dose to the thumb and index finger at 25 sievert (2500 rem) shallow dose equivalent (SDE). A medical professional who had experience with acute radiation exposures assessed Individual A approximately 2 weeks after the event. Information provided to the licensee by the medical professional indicated that he did not observe any affects attributable to radiation exposure, e.g., erythema or blister formation. The mean acute dose for induction of erythema is 6 sievert (600 rem) and for blister formation is 20 sievert (2000 rem).

Following the AIT, additional interviews of licensee personnel identified two witnesses of the exposure event of March 31, 2000. One witness indicated that they observed Individual A handle the generator column in his right hand (versus left) for approximately ten seconds. The second witness relayed similar information. Based on this information, the dose to the tips of the right index finger and thumb would have been approximately 5 sievert (500 rem). **The licensee's failure to control the occupational extremity dose of this individual to the limit of 0.5 sievert (50 rem) SDE constitutes an apparent violation of 10 CFR 20.1201(a)(2)(ii).** The NRC was not able to resolve the differences between the descriptions of the event.

Mallinckrodt's investigation of the exposure event identified one additional example in which an employee touched a generator column. In February 2000, another licensee contract employee used his index finger to guide a (6.4 curie) column back into the shield. The employee believed that the speed with which he performed the operation would not result in any significant dose. Based on reenactments, the licensee estimated the contact time to be one second, resulting in a calculated dose of 0.17 sievert (17 rem) SDE. Neither the licensee nor NRC identified any additional examples of personnel directly handling unshielded generator columns.

Indium-111 Vial Hand-Labeling Exposures

Details of this exposure event are also contained in Inspection

Report 030-00001/2000-002(DNMS). In summary, licensee personnel working third shift in the "other *in vivo*" laboratory applied labels by hand to vials containing an indium-111 product. Each vial contained nominally 740 megabecquerels (20 millicuries). When applying the labels, some of the employees held the vials with their thumb on the bottom, in close proximity to the radiative material. These employees labeled several hundred to several thousand vials each year. **The licensee's failure to use procedures and engineering controls to achieve occupational extremity doses to third shift "other *in vivo*" laboratory personnel that are as-low-as-is-reasonably-achievable (ALARA) constitutes an apparent violation of 10 CFR 20.1101(b).**

Mallinckrodt conducted a thermoluminescent dosimeter (TLD) study to calculate the surface dose rate at the bottom of the vials. Using production records, which included the initials of the individuals who worked the vial labeling station, the licensee determined the total number of vials hand labeled by those workers who held the vials with their thumbs on the bottom. Through interviews of the workers, Mallinckrodt determined the average time that each held the vials while labeling them. With this information, health physics (HP) staff estimated the dose to the thumb of the individuals who received extremity exposures in excess of the NRC limit over the period between 1994 and 1999, inclusive. A summary of the dose estimates that exceeded 0.5 sievert (50 rem) is provided in Table 1. Mallinckrodt did not identify any exposures in excess of the limit for 1994.

Identity	1995	1996	1997	1998	1999
B		1.88	1.38	1.62	0.53
C			3.72	2.45	2.19
D		0.99	0.69	4.79	4.87
E			2.95	3.33	5.91
F				3.05	
G			0.76		
H	0.77	0.85	0.68		
I	1.28	2.10	0.50		
J	2.54	0.73			
K		0.83			

Table 1 - Estimated Annual Shallow Dose Equivalents (sievert)
Associated with Indium-111 Vial Hand Labeling
NOTE: 1 sievert equals 100 rem

Following the AIT inspection, Mallinckrodt reviewed its dose assessments with the affected employees. During this review, the licensee determined that it had misidentified the initials of some workers from the production records. As such, it had assigned the extremity dose from some production runs to the wrong employees. As of the inspection, the licensee continued its interviews of the workers to correctly assign the extremity doses from the indium-111 production runs. **The licensee's failure to control the occupational extremity dose of third shift "other *in vivo*" laboratory personnel to the limit of 0.5 sievert (50 rem) SDE constitutes additional examples of an apparent violation of 10 CFR 20.1201(a)(2)(ii).** The licensee continued its assessment of the total extremity dose (indium-111 product vial labeling dose and dose

received from other routine operations) for those workers identified in Table 1. Mallinckrodt expected to provide the results of that assessment by August 28, 2000.

After determining that it had misapplied the initials in the production records to some workers, the licensee identified eight individuals (versus four at the time of the AIT inspection) who no longer worked at its facilities and who it has not been able to contact. Depending on the method those persons used to hold the vials containing indium-111, their exposures could exceed 0.5 sievert (50 rem) SDE in a year. Mallinckrodt continued its attempts to contact those persons.

Sterility Laboratory Exposures

The third event reviewed by the AIT included extremity exposures received by Mallinckrodt Quality Control (QC) staff working in the Sterility Laboratory. During product sterility testing, laboratory personnel removed an aliquot of material using aseptic techniques from a sample of each batch of injectable products it manufactured. Due to significant concern for the maintenance of aseptic conditions, the QC staff did not always use syringe shields when removing aliquots. In addition, tops were not routinely used on vial shields, and at least one employee held vials in place with the thumb of the left hand when the vial was inverted to remove the test sample. This practice placed the thumb in close contact with the radioactivity, separated only by the thickness of the glass vial. Other individuals completely removed the vials from their shields and held them in their hands while withdrawing the sample. **The licensee's failure to use procedures and engineering controls to achieve occupational extremity doses to Sterility Laboratory personnel that are ALARA constitutes another example of an apparent violation of 10 CFR 20.1101(b).**

Dose determinations for Sterility Laboratory personnel who handled unshielded containers of radioactive material were complicated by the number of different isotopes and products handled by the workers, and the variation of technique among the individuals withdrawing the test samples from the product vials. Through review of testing logs, interviews of laboratory personnel, observation of their techniques handling syringes and vials, and dose calculation software (MicroShield), licensee HP staff estimated the dose to the extremities of the workers. The estimated doses for the Sterility Laboratory workers who received extremity exposures in excess of 0.5 sievert (50 rem) SDE are provided in Table 2. **The licensee's failure to control the occupational extremity dose of sterility laboratory personnel to the limit of 0.5 sievert (50 rem) SDE constitutes additional examples of an apparent violation of 10 CFR 20.1201(a)(2)(ii).**

Identity	1997	1998	1999
J	0.81	0.90	0.68
L	0.81	0.96	0.81
M		0.76	
N	0.93		

Table 2 - Estimated Shallow Dose Equivalents (sievert)
Associated with Sterility Laboratory Testing
NOTE: 1 sievert equals 100 rem

Following the AIT, Mallinckrodt decided to refine its dose calculations for these

workers, due, in part, to the inherent limitations of the software used (MicroShield). In summary, the software does not provide reliable results at small distances (less than one centimeter) and especially at contact. Because of those limitations, Mallinckrodt plans to perform TLD studies to assist in refining the extremity dose calculations received by those personnel. Due to the complexity and magnitude of the assessment, the licensee did not have a definitive date for completion of the study. Mallinckrodt committed to include the study and assessment in its response to Section IV.C. of the Confirmatory Order Modifying License (Order) issued by the NRC on June 22, 2000. That Section of the Order requires the licensee to review past operations to determine if other overexposures occurred. Mallinckrodt is required to provide its plan and implementation schedule for performing that review to the NRC by September 20, 2000.

c. Conclusions

Based on inspection activities conducted after the AIT inspection, the NRC revised its extremity dose assessment for Individual A. The revision identified the right index finger and thumb (versus the left extremities) as the exposed extremities and determined that the dose was approximately 5 sievert (500 rem) SDE. Due to the lack of physical symptoms attributable to radiation exposure, this estimate is more accurate than previous estimates of between 17 and 25 sievert (1700 and 2500 rem). The NRC's medical consultant did not expect any health effects from the exposure. The NRC will review the results of the licensee's revised dose estimates for third shift "other *in vivo*" and sterility laboratory staff when they become available.

2.0 Radiation Safety Committee Oversight

a. Inspection Scope

The inspection included a review of the program oversight provided by Mallinckrodt's Radiation Safety Committee. The review focused on committee oversight provided to new operations and included reviews of committee minutes and associated records, and interview of licensee personnel.

b. Observations and Findings

Mallinckrodt completed construction of a new molybdenum-99 generator manufacturing line and began startup testing in early 1995. Minutes of the Radiation Safety Committee meeting of May 4, 1995, indicated that the line had been completed. During the construction and startup phase of the line, the licensee established an oversight group. Radiologically, the group focused a significant portion of its attention to the generator shielding design and radiation profiling, and certification of the packaging to meet Department of Transportation requirements. A review of Radiation Safety Committee minutes for calendar years 1993 through 1996 did not identify any radiological evaluations of the new manufacturing line by the Committee.

Section 3.4 of Mallinckrodt's Radiation Protection Program, last revised on December 23, 1993, and originally submitted with its December 26, 1991 application for license renewal, which is referenced in Condition 20.A. of License No. 24-04206-01, requires that the Radiation Safety Committee perform radiological evaluations and approve all new uses of radioactive material. **The Committee's failure to perform a radiological evaluation of the Dry-Top-Eluting (DTE) generator manufacturing line constitutes an apparent violation of Condition 20.A. of the license.**

Due to the time since the licensee began use of the new line, the inspector was not able determine the root cause of the apparent violation. Since the generator line began operation, Mallinckrodt began at least two other operations involving byproduct material

(rhenium-186 and samarium-153) for which the required evaluations were performed. In addition, the licensee will begin a new operation involving lutetium-177. The Committee had reviewed preliminary information provided for the manufacture of that product and had given approval for cold (non-radioactive) runs. Based on lessons learned from those operations, the Committee would then give its approval for a production run using a smaller quantity of radioactive material, and then would give final approval for full production. The licensee expected to begin the first cold run in the fall of 2000. The NRC will review the licensee's progress and Committee oversight during the startup of this new product.

c. Conclusions

For reasons that could not fully explained, Mallinckrodt's Radiation Safety Committee did not perform a radiological evaluation of the DTE generator. The failure likely did not contribute to the March 31, 2000 exposure incident. As detailed in the AIT Inspection Report, the rework operation involving manipulation of the column inlet needle was not widely known by licensee personnel outside the Kow Laboratory; therefore, details of the operation would not have been provided to the Committee for it to meet its obligation in this regard.

3.0 Root Causes of the Exposure Events

a. Inspection Scope

The inspection included a review of the root and contributing causes of the three exposure events described in the AIT Inspection Report.

b. Observations and Findings

Individual A indicated that he believed that the gloves that he wore provided adequate protection when he held the generator column in his hand. This belief was based on his misunderstanding of the difference between radioactive contamination and radiation. Since the radiations emitted from the column were gamma rays and bremsstrahlung photons, the gloves provided no significant protection. This misconception was limited to Individual A. Interviews of licensee staff who worked in the Kow Laboratory indicated that all were aware that handling a column was poor practice, but none were cognizant of the magnitude of the surface dose rates involved. The other individual discussed in Section 1, who briefly touched a column to guide it back into the shield, believed that the speed with which he performed the task afforded him adequate protection. He understood that the surface dose rates could be significant, but did not know the magnitude for certain.

As described in the AIT Inspection Report, Mallinckrodt had historically assigned occupational extremity doses to its personnel based on the results of personnel monitoring devices. Licensee supervisory personnel and HP staff had known that some workers directly handled unshielded containers of radioactive material during routine operations, such as during indium-111 product vial labeling and Sterility Laboratory operations. However, they failed to recognize the significant differences between the dose recorded by the monitoring devices and the fingertips. In some instances, the doses to workers fingertips were 100 times higher than that recorded by the monitors when handling unshielded containers. **The licensee's failure to make reasonable and necessary surveys to ensure that the assigned SDE was for the part of the extremities receiving the highest exposure constitutes an apparent violation of 10 CFR 20.1201(c).**

A contributing factor to the exposures in the Sterility Laboratory, was the concern by personnel in that area that the introduction of additional shielding and other regularly accepted radiation protection practices could result in false-positive sterility tests. False-positive tests would result in the unnecessary rejection of an entire manufacturing lot. Although previous audits had recommended the use of additional vial and syringe shields in the laboratory, staff were reluctant to incorporate them since personnel monitoring results were within regulatory limits and due to their concern for false-positive test results.

c. Conclusions

The root cause of the exposure resulting from handling the generator column was the individual's misunderstanding of the difference between radioactive contamination and radiation. The individual believed that the gloves he wore provided him adequate protection since he perceived the radiological hazard to have been contamination, rather than penetrating radiation. Based on interviews of numerous licensee staff, this perception was limited to the individual.

The cause of the other exposures was the failure of plant staff and management, including HP personnel, to recognize the significant differences between radiation doses recorded by extremity monitoring devices and fingertip doses when handling unshielded containers of radioactive material. In some instances, the fingertip doses were 100 times the doses recorded by the monitors. This misconception contributed to the failure of Sterility Laboratory personnel to consistently use syringe and vial shields to maintain their extremity doses ALARA. Laboratory and HP personnel did not recognize the radiological impact of their actions, since they relied almost exclusively on the results of personnel monitoring, which indicated that doses were within regulatory limits. The lack of an aggressive questioning attitude toward extremity doses in the areas reviewed during this inspection directly contributed to the high exposures.

4.0 July 31, 2000 Exposure Incident

a. Inspection Scope

The inspection included a special review of a July 31, 2000 incident, involving the mishandling of a generator column containing 700 gigabecquerels (19 curies) of molybdenum-99. The review included interviews of licensee personnel involved in the incident, records associated with the incident, and observation of the August 4, 2000 generator production run.

b. Observations and Findings

Sequence of Events

The inspection independently verified the sequence of events associated with the July 31, 2000 incident. On July 31, 2000:

- Generator manufacturing personnel rejected column 19.0-04 (fourth column in the manufacturing sequence that contained 700 gigabecquerels (19 curies) of molybdenum-99) due to a broken needle.
- At the end of the planned generator run, the acting area coordinator loaded another column with 700 gigabecquerels (19 curies) of molybdenum-99 (column designated 19.0-60).
- Column 19.0-60 and a non-radioactive column were autoclaved for sterilization. The only visible difference between the two columns was a piece of tape placed

on the radioactive column. (NOTE: Certification requirements for the autoclave required a minimum of two columns.)

- Following sterilization, column 19.0-60 was loaded into a shield and the generator was manufactured following the licensee's normal procedure.
- At the assay station, the operator received a low assay warning for column 19.0-60. The warning indicated that approximately 700 megabecquerels (19 millicuries) of technetium-99m had been eluted from the column, which was outside the expected range of 150 to 260 gigabecquerels (4000 to 6900 millicuries). However, the acting area coordinator and the operator confirmed that the sample volume was acceptable. This indicated adequate flow through the column and a potential problem with column loading, or tagging. (NOTE: According to Mallinckrodt's manufacturing procedures, the generator should have been set aside for a second assay.)
- The acting area coordinator believed that the non-radioactive column, used to balance the autoclave, had been loaded into the shield by mistake. Based on this belief, the acting coordinator decided not to send the generator for a second assay. This decision was not questioned by other staff in the laboratory.
- Generator was moved to the rework station of the manufacturing line.
- The acting area coordinator informed the technicians in the rework area that the wrong column had been loaded and that they to recover the shield to load the correct column. This required removal of the column currently in the safe.
- One technician questioned using a spare depleted uranium shield rather then trying to recycle the shield in the rework area. The individual was told there were none in the laboratory. (Two additional depleted uranium shields were located in the laboratory later in the day.)
- The acting area coordinator provided the technicians at the rework station with a survey meter to survey the generator prior to removing the column.
- A technician surveyed the generator. The technician recalled the instrument reading 85 microsievert (8.5 millirem) per hour, which he verified twice. He interpreted the survey results to be indicative of background radiation levels in his work area during normal operations. (NOTE: Information provided by the licensee indicated that a 700 gigabecquerel (19 curie) generator would have measured between 0.8 and 1.2 millisievert (80 and 120 millirem) per hour.)
- After performing the survey, the technician asked for forceps to remove the plug and column; however, he did not wait for them. He held the exposed column by the needles above the plug, and pulled the plug and column out of the safe. (NOTE: There was no procedure for handling cold columns inadvertently placed in a safe and procedure 5-82 for working with loaded generators specifically states "Under no circumstances is the plug and column to be removed from the safe.")
- The technician placed the column in the shielded rework glove box for later disposal.
- Laboratory personnel loaded the second, non-radioactive column into the shield and the generator proceeded through the manufacturing process to the first assay station. Due to either equipment or personnel error, the generator could not be assayed and was sent, per the procedure, to the second assay station for evaluation.
- The acting area coordinator went to the rework glove box to place the column that he believed was non-radioactive into a shielded container for decontamination. He noticed a brown stain on the alumina, indicating that the column had been loaded with molybdenum.
- Measurement of the second assay of the generator did not detect any radioactivity.
- The acting area coordinator recognized that the 700 gigabecquerel (19 curie) column had been misidentified as non-radioactive and mishandled, and informed the laboratory supervisor.

Extremity Dose Calculation

Following the event, licensee HP staff estimated the dose to the technician's hand. The technician wore his extremity monitor on the ring finger of his right hand, which was the hand he used to hold the column. The monitor recorded a dose of 0.78 millisievert (78 millirem). Based on that data, Mallinckrodt calculated the dose to the tip of the worker's little finger, which was the closest to the column, to be 3 millisievert (0.3 rem) SDE.

Root Cause Determination

In response to the March 31, 2000 event, and other similar examples of personnel directly handling unshielded containers of radioactive material, Mallinckrodt provided instruction to all radiation workers. The instruction included procedural adherence and the direction to personnel to stop an activity if they could not follow a procedure or if they were in a situation that was not covered by a procedure. In addition, each employee received and signed a document stating: "You are hereby instructed not to perform a process step or function and/or other job related duties unless there is a procedure that you have reviewed and been trained on for the same. If you have any doubt or question, contact your supervisor."

Interviews of the individuals associated with the July 31, 2000 incident, indicated that each knew of the expectation to follow all procedures. The individuals also indicated they that were aware of the requirement to stop an activity if they could not follow the written procedure or if their activity that was not covered by a procedure. The interviews were not able to reconcile these acknowledgments with the sequence of events on July 31, 2000.

Interview of the acting area coordinator determined that he had performed in the capacity of acting area coordinator on only two prior occasions. The individual normally worked the early shift manufacturing columns in the hot cell and had not worked on the portion of the generator manufacturing line outside the hot cell for some time. Further, he had never worked at the rework station and was not familiar with its procedures. Mallinckrodt did not provide the individual with training on the technical aspects of the generator manufacturing line or recent changes to procedures made in response to the March 31, 2000 event, prior to having him take over supervision of the laboratory. The training he received addressed the administrative aspects of the coordinator position.

The assay station operator neither questioned the decision not to send the first generator for a second assay nor questioned where the activity was coming from if not the generator. The individual did not believe that it was her place to question decisions made by the acting area coordinator, who had considerably more experience than she. Neither rework station technician questioned the decision not send the generator for a second assay.

The technician who removed the column from the shield failed to properly respond to the results of the survey he performed. The technician's inappropriate, non-conservative interpretation of the survey results led him to believe that he was holding a non-radioactive column, rather than a 700 gigabecquerel (19 curie) column. The surface dose rate of a 700 gigabecquerel (19 curie) molybdenum-99 column is approximately 0.5 sievert (50 rem) per second. Had he held the column by the barrel, rather than by the needles, the resulting dose to his fingers would have been in excess of the regulatory limit of 0.5 sievert (50 rem) SDE. **The failure of the technician to make a reasonable and necessary survey under the circumstances to ensure that**

extremity doses are within regulatory limits and are ALARA constitutes an apparent violation of 10 CFR 20.1501(a).

While the individuals involved in the incident had been trained and appeared to understand the training, the licensee did not have a method for evaluating application and retention of the information by individual workers. Since the generator manufacturing staff were not required to have production procedures in hand, the licensee relied on workers' memory of the procedures, their limitations and precautions. The licensee indicated that it would evaluate the use of additional methods to assess the adequacy of each individual's understanding the off-normal aspects of the procedures.

Licensee Corrective Actions

Following the event, the licensee conducted facility-wide meetings to inform all employees of the event and the associated issues. The licensee conducted followup meetings with individual manufacturing areas to provide more detailed information on material handling and production. In addition, Mallinckrodt formed a four person root cause determination team to evaluate the event.

Short term corrective actions included the meetings discussed above, and removing the acting area coordinator and one technician from the generator production line pending further evaluation. In addition, the plant manager assigned the generator laboratory supervisor and the HP supervisor to the generator laboratory whenever generators were manufactured. If either individual was not present, the production line was to be shut down.

The licensee also developed a long-term corrective action plan to address recommendations from the root cause assessment team. One such recommendation included modifying a non-radioactive column to be used when autoclaving one active column. The modifications would physically prevent the non-radioactive column from being loaded into a generator shield.

Based on direct observation of the production line and discussion with individuals working the line on August 4, 2000, the inspector verified that individuals were aware of the event, knew what was expected from a procedure adherence perspective, and were more sensitive to raising questions to their supervisors. The inspector also verified that the generator laboratory and HP supervisor were both present during generator manufacturing.

c. Conclusions

The July 21, 2000 event, was caused by failures in manufacturing oversight and inappropriate individual actions. Mallinckrodt did not provide sufficient and effective training to the acting area coordinator to allow him to properly supervise manufacturing operations. The individuals directly involved with the event, including the acting area coordinator, did not question: 1) the failure to follow existing procedures; 2) the performance of activities that were not covered by a procedure; or 3) the source of radioactivity in the first assay. When presented with the possibility of having either a non-radioactive column or a 700 gigabecquerel (19 curie) column in a generator, the individuals either failed to properly evaluate the situation or were not confident in their responsibility and ability to question the decisions that the acting area coordinator had made.

The dose to extremities of the technician who removed the column from the safe was not significant. However, considering his belief that he was holding a non-radioactive column and the fact that he could have held it in any manner, there was significant potential for an exposure in excess of the 0.5 sievert (50 rem) SDE limit.

The licensee's corrective actions, including the direct observation by two supervisors, were adequate to preclude similar events.

5.0 Licensee Corrective Actions

a. Inspection Scope

The inspection included a review of the licensee's corrective actions for the exposure events and their root causes. The review included interviews of licensee personnel, the licensee's 30-day reports to the NRC regarding the exposures, and the specific elements of the June 22, 2000 Confirmatory Order Modifying License (Order).

b. Observations and Findings

Following identification of the March 31, 2000 exposure event, Mallinckrodt generator rework operations involving removal of the column from the shield. The licensee also began its investigation into other examples of personnel directly handling unshielded containers of radioactive material. That investigation identified the events involving hand labeling of the indium-111 product vials and Sterility Laboratory activities.

Mallnickrodt's initial corrective actions focused on prohibiting further direct handling of unshielded containers of radioactive material and instructing its staff regarding that prohibition. The licensee provided additional training to plant personnel to inform them of the hazards associated with direct handling. Mallinckrodt also contracted with an independent organization to perform assessments of its radiation safety program and manufacturing processes, and another organization to provide root cause investigation training to a selected group of plant and corporate personnel. Other corrective actions are detailed in the licensee's 30-day reports of the exposures, dated May 12 and 26, 2000.

Due to concern for the events that resulted in the exposures in excess of regulatory limits, the NRC issued a Confirmatory Order Modifying License (Order) on June 22, 2000. The Order required Mallinckrodt to: 1) retain an independent organization to assess the radiation protection program and the radiation safety aspects of its radioactive material manufacturing processes; 2) provide assurances that radiation workers had received training and understood the procedures and practices to maintain radiation exposures ALARA; 3) develop a plan to review operations for the previous 5 years to determine if any individuals received exposures in excess of regulatory limits; and 4) request an amendment to incorporate a corrective action program into its license. The Order included milestones for the completion of each of the elements. Additional long-term, programmatic corrective actions will likely result from the assessments of the radiation protection program and manufacturing processes.

c Conclusions

Mallinckrodt's proposed corrective actions addressed the root causes of the exposure events and were adequate.

6.0 NRC Medical Consultant

a. Inspection Scope

The NRC contracted with a medical consultant to review the March 31, 2000 exposure incident. The consultant reviewed the likely magnitude of, and the possible health effects from the exposure. The inspector also discussed the details of the other exposure events with the consultant.

b. Observations and Findings

During the period from 14 days to 36 days after the March 31, 2000 exposure event, a physician specialist associated with neither Mallinckrodt nor the NRC saw Individual A on several occasions. The specialist did not observe anything resembling redness (erythema) or blister formation on the tips of the thumbs and index fingers of either the left or right hand. These observations were relayed to the NRC's medical consultant. Based on the observations, and the calculated dose to the extremities, the NRC's medical consultant did not expect Individual A to experience any health effects from the exposure.

Since the exposures from indium product vial hand labeling and Sterility Laboratory activities were chronic, the NRC's medical consultant did not provide an opinion on the possible health effects of those exposures.

7.0 Notifications and Reporting

a. Inspection Scope

The inspection included a review of the licensee's identification of each of the exposure events and the subsequent notification and reporting of the events to the NRC. The review included interviews of licensee personnel and the licensee's May 12, 2000 and May 26, 2000 reports.

b. Observations and Findings

On the late morning of April 13, 2000, during the initial investigation of a weekly extremity exposure to a generator manufacturing technician that was in excess of the licensee's administrative limit of 20 millisieverts (2000 millirem), Mallinckrodt HP staff recognized the potential for the individual's extremity exposure to exceed 2.5 sievert (250 rem). The actual exposure incident occurred on March 31, 2000. The licensee notified the NRC Operations Center of the March 31, 2000 incident, at 12:59 p.m. (CT) on April 13, 2000.

During its followup investigation to that event, Mallinckrodt identified the additional exposure events. The licensee's Radiation Safety Officer (RSO) notified the inspector by telephone on April 28, 2000 of the indium vial labeling exposure events. On May 2, 2000, the RSO discussed the Sterility Laboratory exposure events with the inspector.

On May 12, 2000, the licensee transmitted a written report of the March 31, 2000 exposure incident. The report included the individual's estimated extremity exposure, the cause of the exposure, and the corrective actions taken in response to the exposure.

On May 26, 2000, the licensee transmitted a written report of the additional exposure events, involving the hand labeling of indium product vials and Sterility Laboratory activities. The report included the estimated doses in excess of 0.5 sievert (50 rem) for the persons involved, the cause of the exposures, and the corrective actions taken in response to the exposures.

Because of the specific circumstances of the July 31, 2000 event, there was not a likelihood that the technician who handled the column by the needles would have received an extremity exposure in excess of the regulatory limit. Mallinckrodt did not notify the NRC of the event.

c. Conclusions

Mallinckrodt's notifications to the NRC Operations Center and written followup reports were timely and contained all required information.

8.0 Exit Summary

On July 19, 2000, the inspector and the Deputy Director, Division of Nuclear Materials Safety, conducted a preliminary exit summary with the licensee. The summary included the apparent violations, their root causes, and the NRC's understanding of Mallinckrodt's proposed corrective actions. On August 31, 2000, following the additional onsite inspection conducted on August 3 - 4, 2000, the inspector conducted a final exit summary. The final summary included discussion of an additional apparent violation, its root cause and the NRC's understanding of the proposed corrective actions. The licensee did not identify anything reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

Rex Ayers, Health Physicist
Ron Bartnick, Manager, Quality/Regulatory Compliance
Roy W. Brown, Director, Regulatory Compliance
Dale Cowen, Manager, Technical Operations, and Chair, Radiation Safety Committee
Ashok Dhar, Manager, Radiological Affairs
Patricia Duft, Corporate Legal Counsel
Michael Frick, Manager, Operations Support
Linda Graham, Manager, Human Resources
Richard Johnson, Vice President, Imaging Operations
Tony Jones, Manager, Manufacturing
Roger Moroney, Health Physicist
James Schuh, Manager, Health Physics, and Radiation Safety Officer
Dale Simpson, Interim Plant Manager

LIST OF ACRONYMS USED

AIT Augmented Inspection Team

ALARA	As-Low-As-Is-Reasonably-Achievable
CFR	Code of Federal Regulations
DNMS	Division of Nuclear Materials Safety
DTE	Dry-To-Eluting
HP	Health Physics
NRC	Nuclear Regulatory Commission
QC	Quality Control
RSO	Radiation Safety Officer
SDE	Shallow Dose Equivalent
TLD	Thermoluminescent Dosimeter